UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA (SOUTHERN DIVISION)

UNITED STATES OF AMERICA, et al, Plaintiff, vs. ASFORA, et al, Defendants.	CR No. 4:16-cv-04115-LLP MOTIONS HEARING JULY 23, 2020

TRANSCRIPT OF MOTIONS HEARING

BEFORE THE HONORABLE LAWRENCE L. PIERSOL,

U.S. DISTRICT COURT JUDGE

ALL APPEARANCES OF PARTICIPANTS IN THIS HEARING WERE REMOTELY BY VIDEOCONFERENCE OR TELEPHONIC CONFERENCE

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PROCEEDINGS ~ July 23, 2000

Before Hon. LAWRENCE L. PIERSOL, Judge

(All appearances at this proceeding are via videoconference or telephonic conference.)

(Proceedings in open court at 12:16 p.m.)

THE COURT: Good afternoon. This is Judge Piersol. I'm going to go through appearances to begin with.

First of all, who's appearing for the Plaintiff United States of America? And by the way, as you appear, if you can't hear me the way I'm speaking now, tell me. Okay? So who's appearing for the United States of America?

MS. ROCHE: Good afternoon, Your Honor. This is Megan Roche appearing on behalf of the United States, and I can hear you fine.

THE COURT: Good. All right.

MS. BAILEY: Good afternoon, Your Honor. This is Ellie Bailey appearing on behalf of the United States. And I can also hear you fine.

MS. SONG: Good afternoon, Your Honor. This is --

THE COURT: Hold on. Hold on. Wait a minute.

All right. Ms. Bailey. Then next, who's

appearing?

MS. SONG: This is Harin Song, also on behalf of the United States. And I'm appearing by telephone. And I can hear you well. Thank you.

THE COURT: All right. Yes. All right. Thank you.

Then for the Plaintiff Dustin Bechtold?

MR. ANDERSON: Robert B. Anderson at May, Adam, Gerdes and Thompson in Pierre, appearing for both plaintiffs Bechtold and Wellman, Your Honor. I can hear you fine.

THE COURT: All right. Good.

Are you Jay Holland?

MR. HOLLAND: Good afternoon, Your Honor. Yes. Jay Holland also appearing for Dr. Wellman and Bechtold.

THE COURT: There is also Veronica Nannis here?

MS. NANNIS: Yes, Your Honor. Good afternoon. Veronica Nannis also on behalf of Doctors Wellman and Bechtold. Thank you.

THE COURT: And then for the Defendant Wilson Asfora?

MR. GEYERMAN: Good afternoon, Your Honor. Grant Geyerman from Williams and Connolly on behalf of all defendants.

THE COURT: All right. Is Benjamin Graham also

on the phone?

MR. GRAHAM: Yes, Your Honor. I'm here. I can hear you just fine.

THE COURT: All right. Then the local counsel, Steve Landon?

MR. LANDON: Yes, Your Honor. Steve Landon and Brett Lovrien are here as well.

THE COURT: And then I understand that Mr. Landon and Mr. Lovrien, you're in one office. And a part of yours, Alex Hagen, is in another office. Is that right?

MR. LANDON: That's correct.

MR. HAGEN: Yes, Your Honor. Alex Hagen.

THE COURT: I'm not seeing you, Alex.

MR. HAGEN: I'm sorry, Your Honor. I'm not seeing anyone on mine. I can't see the video. I've lost the video. But I don't have a speaking role, so I'm content to just listen. I don't know what the issue is.

THE COURT: All right. All right.

THE CLERK: Mr. Landon, you're giving feedback. Would you mute your mic when you're not speaking, please?

THE COURT: All right. It's the defendant's motion, so the defendant will lead off. And identify yourselves again before you speak.

MR. GEYERMAN: Thank you, Your Honor . This is

Grant Geyerman. Myself, along with my co-counsel, have the pleasure of representing Dr. Wilson Asfora and his two wholly owned medical device companies.

Approximately 30 years ago Dr. Asfora came to Sioux Falls after receiving his educational medical training in his native Brazil and from institutions such as Oxford and Brazil. He's nationally recognized and likely is the most accomplished neurosurgeon ever to practice in Sioux Falls, if not the entire state. Unfortunately, this misguided lawsuit, filed originally by two younger surgeons who competed for patients with Dr. Asfora and now joined by the Department of Justice that intervened as a principal party in interest, has tarnished that reputation in the final years of his career.

All three defendants, Dr. Asfora and his two wholly owned medical device companies, have moved to dismiss the complaint in its entirety. In the complaint the government is asserting violations of the Federal False Claims Act under one of two distinct theories of liability. One theory is premised on the supposed taking and receiving of kickbacks, and the other is predicated on Dr. Asfora having performed unnecessary surgeries on federal healthcare beneficiaries.

And while the complaints -- the government's

complaints and its brief at times blurs the line between these two theories, in doing so it obscures the clear legal and pleading deficiencies with each theory. They are, in fact, separate theories, and we're going to talk about them today separately.

As to each theory, the defendants have three separate and independent grounds upon which that claim can be dismissed and should be dismissed. The first and predominant theory in the complaint, what we've called the ownership kickback theory, is not actually where I'd like to start the presentation today. Given that you're most interested in the medical necessity theory, that's where I would plan to start. My colleague, Mr. Graham, will handle our presentation on the ownership kickback theory, if that's acceptable to Your Honor for us to split the argument.

The False Claims Act, which is the principal cause of action that's asserted in this case, has three prima facie elements: One, false or fraudulent claim for payment. Two, that the defendant acted knowingly; the mens rea component to the statute. And third, that the falsity was material to the government's decision to pay.

This is an Anti-Fraud Statute. It's not in statute intended to police compliance with regulatory regimes or to substitute for a medical malpractice action.

It's a fraud statute. And because it's an Anti-Fraud Statute, the heightened pleading requirements of Rule 9(b) apply in addition to the normal requirements of Rule 12(b)(6), and we have arguments that are predicated on each of those rules independently.

So to start, Your Honor, we sent a couple of hours before the hearing here some slides to your chambers. We sent them to opposing counsel as well. I don't know if you got a copy of them or not. There are just a few of them. But I may reference those slides during our presentation just to orient us all where we're at.

And in -- I'll start with slide three, which is a slide that lists both the ownership kickback theory and the separate and independent arguments that we have for dismissal of those claims, and separates the bases for dismissal of the medical necessity theory claims. And as they say, I want to start with the medical necessity --

THE COURT: Oops. I just lost you.

MR. GRAHAM: I think I hit space bar and muted.

THE COURT: Now you're back.

MR. GEYERMAN: Okay. Thank you. As to the medical necessity theory, we have three independent grounds for dismissal: One, the complaint has not sufficiently alleged repetitive surgeries to support a

false claim on a medical necessity theory; meaning, a surgery that the allegations demonstrate was medically unnecessary for a federal beneficiary for which a claim for payment was submitted to the government.

Number two, that the complaint's allegations do not demonstrate that Dr. Asfora's surgeries qualify as medically unnecessary under the law.

And three, that the complaint contains insufficient allegations to demonstrate scienter, as needed under the False Claims Act, meaning that Dr. Asfora knew or recklessly disregarded the possibility that his surgeries were medically unnecessary.

Each of those grounds is independent of one another. And if one of the three is granted, all claims associated with the medical necessity theory would be dismissed.

Now, before I get into more detail, I would note at the outset that the principle under which the first and the third of those arguments are based is not a real principle that the government seeks. Rather the battleground in this case is whether the complaint's allegations moot that principle.

As to the second argument, we do have a disagreement about what the government's legal rule is. Because as I understand the government's position, they're

saying that per se a trial court cannot dismiss on a motion to dismiss claims because the allegations are insufficient to demonstrating lack of medical necessity.

We disagree with that, based in part on these four cases cited in our brief where other trial courts have dismissed claims for inadequate allegations of a lack of medical necessity of the motion to dismiss. But we are in agreement on the governing legal principle for two of these arguments, and we dispute it at the third. So let me just say that at the outset.

Moving to discussion, then, of the first legal ground, that there are not sufficient representative examples of a claim that could be false under this theory, within the Eighth Circuit it is well established precedent that the government later has to prove, quote, "some representative examples," end quote, of the violation of a False Claims Act, unless the plaintiff has personal knowledge of the false claim or otherwise the allegations bear sufficient indicia of reliability.

This principle indicates back to the *Joshi* case from the Eighth Circuit from 2006 and was reaffirmed as recently as last year in the *Strubbe v. Crawford County Memorial Hospital* case. And the principle is that this is a fraud statute, and under line B you have to plead fraud with particularity. And as a manifestation of that in the

Eighth Circuit, you need to prove some representative examples of a false claim.

The government's position here is not that every surgery that Mr. Asfora performed was medically unnecessary, nor that the government and the two relaters were in the surgeries when they were performed so they don't have personal knowledge of this. Therefore, they are required to follow the representative sample rule that is a requirement in the Eighth Circuit. And so you need to, when scrutinizing the public's allegations, look for three things, three requirements:

One, was the surgery of a federal beneficiary?

Two, were there claims for payments put in to the government for that surgery?

And three, are they adequately alleging that the surgery was medically unnecessary?

If the surgery doesn't check all three of those boxes, it's inadequate to demonstrate a sample violation of the False Claims Act under a medical necessity theory.

And so, to try to respond to where I think perhaps, Your Honor, might find this argument of most assistance, we prepared slide four of our set of slides, which is a table that lays out the 21 different patients for whom a surgery is referenced in the complaint. They're listed in complaint number order.

And we have in the three red columns to our table, is there an allegation that they're a federal beneficiary, is there an allegation of a claim for payment, and what if anything is said on the issue of medical necessity.

And so early in this complaint, the first 260 pages -- sorry, paragraphs, that is -- there's lots of references to difference surgeries that were performed on federal beneficiaries for whom claims for payment were submitted to the government. But not -- for not one of those surgeries is there any suggestion that the surgery was inappropriate or much less that it was not medically necessary.

But then there's a pivot in the complaint to a section that tries to leave the impression that there were some surgeries that were performed that were not medically necessary. And there's really only four surgeries that are alleged where there's any discussion at all about was this a good surgery or not, and that's rows 18 through 21 of our table. And for three of those four, they're not even federal beneficiaries, and there's no reference to a claim for payment. For all we know they had private insurance and the government had no role in that surgery at all. Only for patient Bonnie, who's on line --

MS. BAILEY: Your Honor, if I could object? I

would object to Mr. Geyerman using any patient names, as protected health information and in violation of HIPAA, and in particular 45CFR164.514, which does not allow names of patients to be identified. So to the extent that Mr. Geyerman plans to read patient names in open court, the government would object.

THE COURT: How can she be identified, then?

MS. BAILEY: Well, this individual could be identified if you can connect the individual's name to the complaint, to the date.

South Dakota is a small community. Sioux Falls is a small community. It's not that difficult to connect the dots. So I think it's inappropriate to utilize names. And we would prefer that -- excuse me.

THE COURT: Surgeries in Sioux Falls, though, come from a fairly wide area. We're a major medical center. We're the major one between Denver, and Omaha, and the Mayo Clinic in Rochester, Minnesota. So we draw from a big area. So I don't know that it's that likely, if that's your argument.

MS. BAILEY: Our preference, Your Honor, is that we utilize paragraph numbers from the complaint, and the objection is noted. But I understand your position.

THE COURT: All right. Go ahead.

MR. GEYERMAN: Your Honor, I intentionally only

used a first name to try to avoid precisely that issue, names in the complaint. So I will proceed cautiously. But I wanted -- I want us to be able to know that we're talking about the same surgery, so that's why I put a name on it.

So we're talking about that one patient's surgery, and she's the only individual for whom she's a federal beneficiary, claim for payment to the government, and there's any suggestion that the surgery is in question.

Under the *Frazier* case out of the District of Arizona that we cited in our brief, every other surgery referenced in the complaint is irrelevant to their assertion that there was a violation of a False Claims Act because he was performing medically unnecessary surgeries. They don't check all the boxes. Those other surgeries don't matter at all.

So let's talk about the four patients, then, whose surgeries the complaint does allege some level of criticism about them. And if you flip in our slides to the next page, slide five, that's a table that drills down in a little more detail about the four surgeries; again, three of whom aren't even federal healthcare beneficiaries.

But what's obvious from the table is that we're

talking about four surgeries that all involve fusing of multiple levels of the spine. And this is four surgeries out of approximately 4,800 during the period of the alleged conspiracy that this person performed, that Dr. Asfora performed. Now that number is not in the complaint; I will admit that. The government didn't provide any denominator that you can assess how frequently --

THE COURT: Where does the 4,800 come from?

MR. GEYERMAN: Your Honor, it comes from counsel's investigation of the facts. And I believe that number has been shared --

THE COURT: Well, wait a minute. This is a motion to dismiss. This isn't a motion for summary judgment.

MR. GEYERMAN: Understood. And I guess -- the only point I can make from the complaint, Your Honor, is the government doesn't identify any denominator from which Your Honor could draw a conclusion about how prevalent in terms of how many total surgeries Dr. Asfora performed these four represent.

And so the allegation about them is that they were aggressive, or quite aggressive; that the surgery might have been more conservative, or that many surgeons would not have performed this surgery. But what the

allegations do not say is that -- they don't say that any of these surgeries were medically unnecessary. They're more equivocal, softer conclusions than that. And frankly, as is evident, this is a debate over how many levels of a spine fusion was appropriate. Was three appropriate, or was four? Was four appropriate, or was five? We are debating a matter of degree in terms of what was the best surgery.

But for purposes of false claims liability, the question is not what is the best surgery that should have been performed, but rather was it medically unnecessary. And I'd submit that when you look at the medical necessity cases where a complaint is found to have plausibly alleging a lack of medical necessity, they're not disputing issues that are a matter of degree, but rather there was no medical value at all to the surgery or to the test or to the prescription drug that was at issue.

And so one would draw a distinction analytically between the criticisms that are a matter of degree, where there's no suggestions the surgery shouldn't have been performed at all, it's rather how many levels of the spinal fusion were appropriate.

And to try to bring this home for Your Honor, if you flip to the next slide, we tried to get as specific as we could about what it is about the nature of these

criticisms of his spinal surgeries, his four surgeries that --

THE COURT: Aside from the individual surgeries, what about the fact that the use by Dr. Asfora, according to the allegations, that his use of the bullet cage increased exponentially as time went on?

MR. GEYERMAN: Several responses. Number one, that is really talking about the other theory of liability that the government is asserting; that he was engaging in kickback schemes and he profited from his sale of the bullet cage. I -- it's notable on these four surgeries that are alleged to have been medically unnecessary, they don't tell you how many implants were used in those surgeries, nor do they allege under the surgery he should have performed that he would have implanted any fewer implants.

Which is to say -- that's a demonstration that there's really no analytical nexus between the complaints they're making about he shouldn't have been operating a medical device company that manufactured devices he used himself. That's one theory. And we're going to talk about why they fail to state a claim under the kickback arrangement.

But completely independent of that is their assertion in performing medically unnecessary surgeries.

In other words, let's take the patient whose name will go unspoken where a four-level fusion was performed on her. The complaint does say that an Aegis screw was used in that surgery. It doesn't say how many screws were used. And it also says the complaint is she -- you could have performed that surgery with fewer levels of fusion.

Okay. But there's no suggestion that if you'd done three levels of fusion instead of four you would have used fewer Aegis screws. We don't even know how many screws got used in the first place.

Our position is that whether something was medically unnecessary analytically is entirely separate and distinct from the question about what implants were used. Because they're making a completely different theory of liability on implants, which is a kickback theory of liability. They're saying it was necessarily tainted because he had an ownership interest in the company supplying devices.

And it's only because, quite frankly, the Anti-Kickback Statute is trying to prevent doctors from overprescribing or performing unnecessary procedures that caused them to enact the kickback statute in the first place.

But there's no actual nexus here between the surgeries that are alleged to have been unnecessary and

his use of more implants than would otherwise had been used had it been the appropriate surgery.

So we view these as separate and distinct legal theories. We think it's important that Your Honor look at them as separate and distinct legal theories. And we think that it's -- as a pleading and tactical matter, honestly. It's really where the government has decided to try to blur the lines between those two theories that the complaint sort of gets confusing. Medical necessity should have nothing to do with whether he owned or didn't own Medical Designs. He either performed unnecessary procedures, or he didn't. It doesn't matter what the implants were that were a part of that procedure.

So, rooting this in sort of the case law that exists with respect to other cases where lack of medical necessity has been asserted, here's where the complaint in this case falls short:

Number one -- this is on slide six where we tried to put citations into other cases and hide them with specific insufficiencies with this one. Number one, there's no definitive allegation of an absence of medical justification for these four surgeries. Remember, three of them don't even matter because they're not even federal beneficiaries. But there's no opinions saying no reasonable surgeon would have performed this surgery. And

again, the standard to have liability for a lack of medical necessity is that there is no medical justification. So you need something akin to no reasonable surgeon would have done "X."

This dispute is a matter of degree. And so really, the foundations in this case are more like the *McFarland* case out of the Middle District of Florida where there the allegation was that the defendant had prescribed certain medications that were not allegedly medically necessary.

And when you scrutinize the complaint, the allegations were that it was highly unlikely that the medication would have some appurtatious benefit for the patient, or it was doubtful that the patient would benefit clinically from the medication. And the Court said that doesn't rise to the level of showing an absence of medical necessity even if it's questionable, highly questionable, whether there would be some effectiveness.

Second, the complaint cites no objective standards underlying the criticisms that are lodged against Dr. Asfora's surgeries. And that really hits home when you look at the case the government showcases in its brief, the *Polukoff* case out of the Tenth Circuit. There it was a doctor who was performing a certain heart surgery. And there was an American Heart Association, an

American Stroke Association guideline that said you do not perform this surgery for any purpose other than to cure, essentially, recurring strokes.

But the allegation in that case was that that doctor believed that that procedure actually helped cure migraines. But because insurance didn't cover the surgery when done to treat migraines, he would misrepresent the purpose for which he was performing the procedure.

And the reason the allegations plausibly alleged a lack of medical necessity is because there was an AMA, or an American Heart Association, an American Stroke Association guideline. That guideline had been specifically adopted by the treating hospital as the operative internal guideline. And their allegation was that, quote, general agreement in the medical community was that that procedure should not be performed for any purpose other than to prevent recurring strokes.

That's the kind of concrete, identifiable standard that should exist if you're going to allege that performing a procedure is not medically necessary. Because if you don't have some sort of third-party objective standard against which to measure whether this surgery was or wasn't appropriate, you're really running into the realm of second-guessing clinical judgments. And the Supreme Court has said that the federal False Claims

Act is not meant to be a statute to punish medical malpractice. It's not meant to be a replacement for the state code that regulates doctors.

This is a fraud statute. And so reasonable differences of medical judgment don't rise to the level of demonstrating a lack of medical necessity. And so the absence of any objective standard that's alleged in the complaint to show why these surgeries at four levels instead of three were medically unnecessary is a legally significant omission.

Number three, the complaint wasn't identified, the details about who the individuals are that rendered these critiques of these surgeries. We're not given names. We're not given full credentials. And it doesn't even -- the complaint doesn't even --

THE COURT: Wait a minute. Wait a minute. That seems to be stretching it a bit. As one of the details you have to have in a complaint, you give the name. That's obviously discoverable, as are the credentials. But to suggest that in the complaint you have to not only name the person that you're quoting, but beyond that that you have to have their credentials, even under a 9(b) standard, which this is, I think that's one that can be required.

MR. GEYERMAN: I'm not trying to set a bright

line rule, Your Honor. Ultimately the standard is have they specifically pled details under the Eighth Circuit's representative sample requirement to sufficiently prove to Your Honor this is a claim that if proven true would be a violation of the statute.

And in the absence of a third-party, an objective standard, in the absence of -- in the circumstance here, again, it's a matter of degree. It's not he should never have performed any surgery on these four people at all; it's that he should have just fused fewer levels of the spine instead of the number of levels that he did.

Our submission is from a holistic consideration of how good are these allegations? Do they warn of chinks going forward into discovery against this defendant? We submit that the fact that we don't even know who these reviewers are is significant. And one reason we don't know is we don't even know their name.

THE COURT: Well, you do -- you'll know them pretty soon if the case goes forward.

MR. GEYERMAN: Well, I'll only know them if they tell me or if I ask. You're right.

And the fourth point I would add is that in some cases when a complaint has been found to not plausibly allege medical necessity, the plaintiff went as far as to

even attach the underlying report of the surgery or the procedure so that when a court is evaluating on a (9)(d) analysis, are there specific details here: Is there enough to have this case survive the pleading stage? I can at least look at the full medical record and report.

The complaint here doesn't do that. Rather --

THE COURT: It was suggestion --

MR. GEYERMAN: -- we only have --

THE COURT: -- can't hear what the -- just a minute.

You're suggesting a standard with an attachment of medical reports and so on to a complaint, that even on a 9(b) I think is beyond the requirements of a 9(b), just so you know --

MR. GEYERMAN: Well, again --

THE COURT: -- to be discovered.

MR. GEYERMAN: I'm not advocating or suggesting that a bright line removal be created. But again, from a holistic evaluation of this complaint, are the allegations sufficiently specific? The fact that they have shared and served certain quotations -- not even complete sentences, I might add, not even a block quoting. This is the entirety of the conclusions section. They've not quoted it.

And we obviously know more about these

procedures than are in the complaint, and if -- we have a lot to say about this. But I'm limiting it to this point as to what's in the complaint, and it's not very much, and they're not even attaching the whole medical record.

So that's our second basis for dismissal of the medical necessity claims, is that there aren't sufficient allegations to demonstrate these -- this one procedure is in fact medically unnecessary.

And with the third and final ground for dismissal of the medical necessity claim is that there are no allegations in this complaint that Dr. Asfora himself actually believed these procedures were medically unnecessary. And that is a fatal omission to this complaint. Because the knowing submission of false claims is a prima facia element of a cause of action. And so not only does the surgery had to have been medically unnecessary --

THE COURT: Just a minute. Just a minute. Let's touch that a little bit. Because there's a claim by the defense that says risk assessment, so to speak, is going to 95 percent. That goes to the top five percent of the risk element. And so -- that he put in his medical notes, I didn't think this was necessary surgery, he obviously isn't going to do that.

So the -- it could be said that the government

gets the opportunity to try and show to a jury that, in fact, he didn't or loosely have significant wording that he was going to -- the situation wasn't medically necessary since the score level is so high.

And what kind of evidence do you extract for ability to show intent? Intent is usually shown by circumstantial evidence.

MR. GEYERMAN: It is typically shown by circumstantial evidence. But they don't have any -- they don't allege any circumstances about him in these surgeries at all.

As to the risk score point, that -- there's very little that's alleged in the complaint about what that risk score means. They call it a risk score, but they don't actually allege very much about that Vanderbilt University scaling score. What they do allege is that it measures patient satisfaction. That's the only concrete fact that is alleged in the complaint about what that measures. And it says that he has a high risk score on a -- on something that leads to customer satisfaction.

So in terms of -- I don't think a fair inference can be drawn between him having a high score on that and the fact that he had some reason to believe that a particular surgery was medically unnecessary. They're certainly drawing no connection between the four surgeries

they complain about and that risk score. There's nothing direct to the complaint to that fact. And I would say that we've cited cases where the Court, in dismissing at the motion to dismiss stage a medical necessity claim, makes note of the fact that there are no allegations that suggest the defendant believed the surgery was unnecessary.

It's a prima facie element. And we're not asking you to obviously judge any evidence in this case, but we are asking that the plausibility of their allegations be scrutinized. And even giving them the benefit of all inferences for what they've alleged, we believe that they haven't plausibly alleged any facts on misuse of scienter, because they don't say anything about him and these particular surgeries.

I guess I would just note that the government in its brief argues that it's essentially impossible for a defendant to prevail on the argument that allegations in a complaint don't demonstrate medical necessity at the motion to dismiss stage. And we cited *McFarland*, *Plavix*, the *Health Management Associates* case infringer that all did the exact opposite. And the conclusion there is not the procedures were medically necessary, but rather the complaint's allegations are not sufficiently plausible and specific to suggest that they're not medically necessary.

That's the specific procedural test before Your Honor, and we don't think that they've done it.

That -- those are our three points for grounds for dismissal of the medical necessity claim. This is not any -- this is not a medical malpractice statute; it's an Anti-Fraud Statute. And we don't believe that they've met their pleading burden.

Unless Your Honor has more questions on that theory, I would turn it over to Mr. Graham to talk about the ownership kickback theory, if Your Honor would like.

THE COURT: All right. No, I don't have any further questions.

I was obviously concerned about medical necessity. That's one of the reasons I keyed it up for people to argue. I'm not so concerned about the owner kickbacks, so we'll see how your partner does on that.

MR. GRAHAM: Thank you, Your Honor. This is Ben Graham from Williams and Connolly. I'll be addressing the second theory that is raised in the complaint, which we have described as the ownership kickback theory.

Now, I'd like to be clear at the outset about what the government's theory of the case is here. On the government's view as expressed in the complaint and the opposition brief, any time a doctor wholly owns a medical device company, uses a device from that company in one of

his surgeries, and then receives his ordinary profit distribution from that company, the government believes that doctor has committed a crime in violation of the Anti-Kickback Statute.

That is a novel and sweeping theory of liability, and it should be dismissed for any one of three reasons that you identified, both in the slides we handed up this morning and also the briefs from this case.

The first reason applies generally as a matter of law. There is no kickback. The complaint fails to even -- does not allege and pursue a cognizable theory as a general matter under the Anti-Kickback Statute. That's true in this case and in every other.

The second theory is more particular to the allegations about Dr. Asfora and Medical Designs in particular. And the second ground is that as applied to Dr. Asfora and his company, the complaint does not adequately allege scienter. The AKS, as you know, is a --

(Static and sound distortion.)

(Reporter asked for clarification.)

MR. GRAHAM: The second ground, Your Honor, is scienter; that under the AKS, that's a heightened mens rea burden, and the government must allege that Dr. Asfora and his companies knowingly and willfully engaged in the unlawful conduct.

And the third ground is that the complaint for similar reasons does not allege materiality, which is a necessary element under the False Claims Act.

Now, I'd like to go through those in order, and I'll try to do so briefly.

So the first is the very nature of this ownership kickback theory. Now under the Anti-Kickback Statute, it criminalizes behavior where two actors exchange financial incentives to encourage the other actor to shift government beneficiaries towards the first's services or medical -- medical services.

Now, the government here in this case is pursuing a novel theory: That a doctor who wholly owns a medical device company kicks back to himself by receiving profit distributions. To our knowledge and based on everything that the government has attempted to put in in the opposition, no court has ever held that that was a viable theory. No agency guidance from HHS has ever reached so far. And indeed, based on the government's complaints that are reached for as attachments to its opposition, it doesn't even appear that the government itself has ever brought a case on that theory, targeting a doctor who wholly owns a medical device company. And that's for good reason.

The AKS focuses on inducement, as the efforts of

one actor through financial incentives to change the behavior of another. The cases we cited to Your Honor say that's the gravamen of Medicare fraud. Here, the AKS violation is inducement.

And I think the clearest case to explain this standard and the structure that we care about when looking at kickbacks is probably the *Patzer* case, from the Eastern District of Wisconsin. We cite that on page 14 of the brief. And I'll just quot a couple of sentences from it, because I think it encapsulates the core of our defense and it's one to which the government has not offered a response.

"The very definition of kickback requires that a person provide something of value; one, to another person; and two, to improperly obtain or reward favorable treatment."

Now those two elements are the very elements that are lacking here. There are not distinct people, and nothing was offered to induce or to change the behavior of the other.

The Court in Pastor continues to say, "Implicit in this definition is the idea that each party of the kickback transaction is acting independently and can choose or could have chosen not to deal with the other. If such independence is lacking, then one party who is

providing something of value for another could not be viewed as incentive."

THE COURT: Let me ask you a question.

MR. GRAHAM: Yes.

THE COURT: According to the allegations, again, Dr. Asfora approached other physicians in saying if you use my bullet, then I'll kickback, frankly, "X" number of dollars for every one that you used. And according to the allegations again, they said I can't do that, that's illegal.

But how is that different than if you consider his corporation to be a separate entity, how is it any different than when Dr. Asfora winds up getting, in essence, a sum of money separate and apart from the surgery that he performed, for doing it? How's that any different from what he offered to do with some other surgeon who turned him down?

MR. GRAHAM: Your Honor, two responses to that. The first is that the alleged payment and his consulting fees to other physicians and other surgeons, those aren't part of this case, because those are investigated and settled and released as part of the DuBay investigation, (indiscernible) 2011 to 2013.

Now as to the hypothetical Asfora approaches another doctor and offers to pay them --

THE COURT: We've got an audio problem a little bit. You're getting scrambled. Let's do a testing. One, two, three, four.

MR. GRAHAM: One, two, three, four.

THE COURT: That was clear. So I think maybe -- Misty? Maybe a little more slowly. You weren't speaking that fast, but it was getting a little bit garbled here. So go ahead. Not that what you're saying is garbled at all, but the way it was coming was garbled, okay.

MR. GRAHAM: I'll ask my computer to be a better messenger.

So the difference is, Your Honor, I think is on a couple of fronts. One of those is that in that context, there is a different actor. And in that allegation, Dr. Asfora alleged to be offering remuneration to a third party for purposes of directing patients towards devices from his company.

In the context of Dr. Asfora and his company directly, you have to look at the verbs in the statute. There is no "offer." There is no "inducement." The there isn't a "solicitation." Dr. Asfora does not need to solicit his profit distribution from his company. His company does not offer the profit distribution to Dr. Asfora. Those terms don't even apply in the context of a wholly owned medical device company; which sets this

apart from all of the other cases the government would like to discuss about the doctor-owned distributorships.

And I think those cases are instructive on this point. Because if you look at the HHS guidance and the special fraud alerts, what they say is that a company that is owned by a physician is not unlawful, but it should be subject to scrutiny.

THE COURT: Well, one of the companies was owned by the physician and his wife. The other one was owned by him solely. Isn't that the case?

MR. GRAHAM: That's right, Your Honor.

THE COURT: What about this one that was with the physician and his wife? Even if you take your theory that he can't solicit himself, what about the fact that there's a third party involved with regard to at least the conspiracy claim?

MR. GRAHAM: So in this context, and under the statute, a physician and his wife are treated as one in the same purposes, one in the same person. The government disregards the distinction between them for the ownership interest. The so that's why I refer to them as wholly owned.

In our opening brief we cited statutory authority for that, which I can flip back to in a moment and probably forward you in response. So there is for

this only one owner, and that is the married entity, and it disregards payments to a spouse.

So in both Medical Designs and in Sicage, for purposes of this statute and for the healthcare laws, there is one owner in both.

And that sole ownership is a distinguishing factor in this case from the others in which the government has pursued claims against entities that have physician owners.

Now, in those cases, Your Honor, I would actually just direct you to the ones the government cites in their brief. If you read those cases, in each of them the entity that was at issue, the pod or physician-owned distributor, was generally a new entity that was created; It was one that solicited investments from multiple different doctors explicitly for the purpose of demanding that they make referrals through that entity, and then siphoning money back through it to disguise cash payments. And the hallmarks of fraud are all over those entities.

For example, in the *Iqbal* case from the Eighth Circuit, someone approached for a business relationship -- the defendant approached another entity for a business relationship where he would direct referrals to that company and demanded a share of the proceed in return. And to get that off the ground, they created, quote, bogus

consulting agreements.

In the *Bruno v Schaeffer* case, also in the government's brief, positions were offered for investments in laboratory entities, but, quote, existed in name only and didn't physically exist and were not licensed labs.

By contrast to all of those cases, there is a sole owner who is a real doctor, who created real companies for the purpose of making real products. Medical Designs was founded in the nineties, so that Dr. Asfora could create his bullet cage, patent that product, get FDA approval for it, and then use it in his operations. That's a far cry from the abusive fraud tactics that are at issue in the other cases the government cites.

And still, in none of those cases has the government sought to bring a charge against a sole owner of a medical device company. That's why this theory in this case is novel and would sweep far too broadly and, frankly, wreak havoc across the entirety of the medical industry. And it has bad policy outcomes, too.

We want expert physicians like Dr. Asfora, who is one of the best and most renowned physicians practicing in the Midwest, to be able to develop products for use in these complex surgeries.

Your Honor, I'd also like to touch briefly on

the second two grounds for why this ownership kickback theory would have to be dismissed in relation to Dr. Asfora in particular. As I said, the AKS is a criminal statute. Under Eighth Circuit law there's a heightened mens rea burden. And under the *Jayne* case what it means is the government has to show that conduct was, quote, obviously evil, or that Dr. Asfora intended to engage in unlawful conduct.

Now, as Your Honor pointed out, mens rea can be established through circumstantial evidence, but there are precisely no allegations in the complaint that Dr. Asfora believed that this was unlawful conduct. There are allegations about what other people said, to be sure. And it's also the case that other companies and other hospitals didn't want to do business with physician-owned entities because they were concerned about precisely this situation. The government has been very aggressive in pushing these theories. There are trouble indicatives under the FCA, and there's good reason why someone in business might want to avoid this as a prophylactic matter. But that doesn't mean that it's unlawful. And in fact, Dr. Asfora had very good reason to believe that his ownership structure was lawful.

The DuBay investigation revealed that he was the owner of Medical Designs, that he was using Medical

Designs for products in his surgeries, and that he was receiving profit distributions from Medical Designs.

The government received that information in a complaint from a relater. HSS, the Office of Inspector General, the very agency responsible for paying Medicare claims, issued subpoenas and investigated the matter and reached resolution. And they did not pursue a claim that the ownership structure was a violation of the AKS.

So in contrast to every other actor who might tread lightly in this area that might be concerned about government overreach, Dr. Asfora had already been through this investigation, and the government had not made a claim on the basis of his ownership structure.

That is the same ownership structure under the entirety of the ownership kickback theory. They believe that the mere fact of ownership, use of the product, and receipt of product distributions violates the AKS. When Dr. Asfora had very good reason that that was not the case, because all let it passed on the very claim.

Now the --

THE COURT: Just a minute. Just a minute.

Now you're saying that because of the DuBay case, that Dr. Asfora has reason to believe that what he was doing was fine? Is that what you're saying?

MR. GRAHAM: Yes. Yes, Your Honor, we are.

THE COURT: So why did he pay $650,000 in settlement?

MR. GRAHAM: Over a different allegation than DuBay, Your Honor. The one allegation was that Dr. Asfora was paying cash payments through the closing agreements to other doctors. That was one of the allegations in DuBay. DuBay overrid the allegation that Dr. Asfora himself was using these products and receiving a product fee. Those are in the complaint. Those are the kinds of information that were sought by the subpoena. And then the actual settlement agreement did not raise as misconduct the receipt of profit distributions. The settlement only focused on the cash payments to other doctors.

And as we discussed earlier in the hypothetical that Your Honor raised, payments to other parties, to third parties, is the kind of thing that creates AKS liability. And in the settlement Dr. Asfora of course admitted -- (sound distorted) -- but the prevailing part is that the government did not pursue a claim in that case that the ownership and profit distribution was also an AKS violation.

So after being sent through the wringer with the government and sitting through subpoenas and with negotiating the settlement with the government, Dr. Asfora had good reason to believe that the ownership part --

THE COURT: Wait a minute. Wait a minute.

The settlement wasn't actually with the government, because the government declined to undertake the case. And so the other parties received it. And under the (sound garbled) proceedings, the government has to give notice of it in case they're going to intercede in order to object to the settlement. So the settlement wasn't with the government. Right?

MR. GRAHAM: Two points, Your Honor. The government -- in false claims cases has right of approval for settlement agreements and can intervene at any time. The government did decline to intervene. But the government also played an active role in that case when it issued the subpoenas and received information about Dr. Asfora's ownership.

THE COURT: Right. But the Anti-Kickback Act requires that they receive the information during the proceedings. But when you look at the pleadings in the case, there wasn't anything in the pleadings. No discovery was reflected. There's not even an answer reflected.

MR. GRAHAM: Well, Your Honor, the discovery happens before the complaint is unsealed. So when the complaint is filed or (indiscernible) files it under seal, the government gets the notice and the government issues

subpoenas, conducts a thorough investigation, and then will make a decision whether or not to intervene before the case --

THE COURT: Yes, I'm familiar with that.

MR. GRAHAM: As you may know from this case, if not from others, the government was involved in that investigation. The subpoenas that we attached to our motion to dismiss, Your Honor, I believe it's ECF number 74-2, is a subpoena issued by HHS which they --

THE COURT: What do you have to say then about even the warnings that he got from his own lawyers that he shouldn't -- you can't do this? What about that?

MR. GRAHAM: Well, Your Honor, the lawyers, as you know, are notoriously risk averse. And Dr. Asfora's counsel advised him that there were risks associated with some of the transactions he was contemplating agreeing to with these other third parties and the licensing arrangements. But they also said that it would expose Dr. Asfora potentially to a qui tam action, could expose him potentially to an action by the government, but that there would be defenses. Dr. Asfora's counsel never told him that this was illegal or unlawful. They did counsel's job and advised him of the risks.

And that advice ended up being correct in that respect. The government has pursued a claim, and it has

led to the result of Dr. Asfora suffering tremendous economic harm. That doesn't change the fact that under the scienter standard, materiality standard, or the basic nature of an ownership kickback, there is no liability under the AKS, despite the government pursuit of it.

And, Your Honor, speaking to the government's role in the DuBay investigation as well, that underpins the third reason for dismissing the ownership kickback theory. And I think it's under the False Claims Act there's a materiality requirement. And under the Supreme Court's reasoned decision in *Escobar*, that is a rigorous standard and it's one that should be enforced on a motion to dismiss.

And here's the issue: Under *Escobar*, if the government is aware of what it perceives to be predicate facts that would indicate that there was an HHS violation, and it does nothing for years and continues unabated to pay the claims that Dr. Asfora submits under that same very ownership structure that the government was on notice of, then under the Supreme Court's holding in Escobar, that is strong evidence that there is no materiality.

In other words, if the government is correct on the first hand that there is this broad, sweeping liability under the ownership kickback theory -- which we contest but they seem to believe there is -- they knew

every predicate element --

THE COURT: (Static and garbled sound.)

MR. GRAHAM: I'm sorry, Your Honor?

THE COURT: Strong evidence. Not that this evidence is strong and this is enough to kick out the claim and so on. Strong evidence doesn't sound like something that a court should be considering in its ruling on the 12(b)(6) motion as opposed to a summary judgment motion.

MR. GRAHAM: Your Honor, courts do dismiss FCA claims on the grounds of materiality on the pleadings. And we're not asking Your Honor to balance the evidence. But the government does have a burden under Rule 8(a) and 12(b)(6) to name plausible inference of a materiality theory, and the Supreme Court emphasizes that this is a rigorous standard.

It's the kind of bait and switch that *Escobar* was trying to prevent. The government knew that Dr. Asfora owned this company and was using these devices. It was front-page news for years. And they allowed him to continue making a claim for payment and paying them. HHS, the same entity that investigated the allegations in DuBay, continued to make those payments . And what the government is not allowed to do under the *Escobar* standard is to lead an doctor down the garden path and then years

later turn around and sue for liability. It's unfair, and it is dismissible under the *Escobar* standard.

So, Your Honor, for any of these three reasons, because the ownership kickback theory at large does not constitute a kickback, because there was no plausible allegation of scienter, even when investigated before, and because the government continued to pay without raising the issue for nearly a decade, each of which is an independent reason that we think the ownership kickback theory should be dismissed. Thank you.

THE COURT: Thank you. I'll hear from the government.

MR. GEYERMAN: Your Honor, before the government starts -- I would just add there are several sort of secondary claims brought for conspiracy, payment by mistake, and unjust enrichment. We're happy to rest on the papers on that, unless Your Honor has questions.

And because Your Honor asked specifically about the settlement agreement from the DuBay case, I direct you to docket number 743. The settlement agreement from DuBay is in the record on the motion to dismiss, and the government is a signatory to that settlement agreement. And a Sanford hospital paid one hundred percent of the settlement payment. There was no payment by Dr. Asfora.

THE COURT: Except that I have the settlement

agreement right here with me, And there's nothing in the record that says that Sanford paid a hundred percent.

MR. GEYERMAN: That part is true; that is not in the record. But I am representing that that is true.

THE COURT: I don't question your representation. I just point that out, you know. Because this is kind of an unusual 12(b)(6) hearing because we're talking about a lot of things, some of which aren't in the record. That's why I make the point. I don't question your representation; on the other hand, I don't accept it as being a part of the record before me.

All right. With regard to the other claims, the unjust enrichment and the other things, the duplicate recovery and all that, you've briefed all that, so I don't have any questions with regard to those.

I pointed counsel specifically to the things I was especially concerned about, which you've covered well in your briefs as well as here. And the other things have been covered adequately already. Well, as to those two issues too. But I'm obviously interested in hearing on the two issues I specified not only from you, but likewise from the government, because those are ones that you've put forward forcefully in your briefing.

All right thank you, then.

Let me hear from the United States.

MS. ROCHE: Thank you, Your Honor. This is Megan Roche, speaking again after you requested that we identify ourselves. Can you hear me okay, Your Honor?

THE COURT: Yes. Go ahead.

MS. ROCHE: Thank you. And may it please the Court, counsel.

The United States respectfully requests that the Court deny defendant's motion to dismiss United States' complaint in intervention.

THE COURT: Just a moment. I've lost my realtime.

(Off the record to resolve technical issues.)

MS. ROCHE: As I was saying, the United States respectfully requests that the court deny defendant's motion to dismiss.

The United States' complaint in intervention, the United States has met the necessary standard in Federal Rule of Civil Procedure 12(b)(6) and then has stated sufficient factual matter. It's well pleaded and accepted as true that the stated claim for relief is plausible on its face.

The United States has acknowledged, just as defendants have already stated, that 9(b) is, of course, at issue in this case as we are discussing matters under the False Claims Act. And so the United States does have

to state with particularity the circumstances constituting fraud. The defendant has already established there are essentially the two theories of the case: The medical necessity claims, and the Anti-Kickback Statute violations. As the Court has suggested it's more interested in the medical necessity claims, there's where I will begin and attempt to respond to the arguments that --

THE COURT: Let me ask you -- just a moment.

On the medical necessity claim, in this complaint there's less detail with regard to specific cases than there was originally. Isn't that correct?

MS. ROCHE: You mean by originally the difference between relaters' complaint and the United States' complaint?

THE COURT: Yes.

MS. ROCHE: Yes, that's a fair -- as far as discussing specific procedures and attacking medical judgment and medical choices and procedures, that's a fair assessment. There was a number of discussions of specific provision violators in the complaint.

THE COURT: Hum. They told us -- (sound garbled).

MS. ROCHE: What's that?

THE COURT: That was the reason for calling

some -- for removing some of the detail, culling some of the detail.

MS. ROCHE: Right, Your Honor. And I'll get to that, as to what I think that the United States' pleading requirement is under 9(b) as to what needs to be pleaded for 9(b) to be satisfied for the medical necessity claim.

And so just a quick snapshot and some background information, considering we've talked about what constitutes medical necessity as defendants began arguing. And of course Medicare and Medicaid only cover services and items that are reasonable and necessary for the diagnosis or treatment of illness or injury.

Of course as the parties already have briefed that if there's a nonreimbursable claim that's submitted to federal healthcare programs, that claim is false. And if a claim is not medically necessary, that is also false. I don't think there's any disagreement about that.

But the defendants have already discussed sort of this degree of difference between medical judgment and that information. I'll get into that a little bit further here. But we did want to discuss in the *Polukoff* case, a Tenth Circuit case, that case -- and we cited it in our briefs -- specifically said that to be reasonable and necessary a procedure must be among other things appropriate, and that includes the duration and the

frequency, and furnished in accordance with accepted standards of medical practice. And then finally, meets but does not exceed patient's medical need.

And that's just one case, *Polukoff*, and it's cited in the brief. And that's something to just keep in mind as I guess into the next argument about what the standard is in the Eighth Circuit as to what the United States has to show under 9(b) at this stage of the litigation regarding the medical necessity claim.

So the defendants have asserted at this stage that it's imperative that the representative sample, the representative or example patient be pleaded at this point. And we would actually disagree with that at this stage and based on the law in the Eighth Circuit. Of course the parties talked about *Joshi* a fair amount, and in the pleadings and also here in argument today, but the Eighth Circuit has a different test. And it was briefly mentioned, but I don't think it was highlighted enough. And that's discussed in the *Thayer* case, the *Thayer versus Planned Parenthood*. And that was cited in our opposition brief. And in *Thayer*, the Court there noticed -- it's a Judge Wollmann opinion -- a party can satisfy Rule 9(b) without pleading representative examples of false claims if the party can otherwise plead that the particular details of a scheme to submit false claims paired with

reliable indicia that lead to a strong inference that claims were actually submitted.

And so that was a case, *Thayer*, that essentially said *Joshi* always saying there must be a representative patient example is not the law. And *Thayer* was a little bit different in the fact that there was a pretty wide Circuit sweep and a Circuit analysis. And I think that *Thayer* discussed or cited at least seven but probably eight other sister Circuits that also talked about the reliable indicia test under *Thayer*.

And so in examining that is sort of where defendants have said that the lines get blurred. And in this instance we do believe that in some respects the lines should get blurred. Because if you're talking about all of the specific and the particular details that are in the United States' complaint, it covers the majority of all the paragraphs in that complaint, a lot of which is talking about the ownership interest, the ownership theory, the alleged kickbacks, the structure and arrangement of the types of distributions that Medical Designs was engaged in, that Sicage was engaged in, that Dr. Asfora was engaged in.

And so to talk about the particular details of the scheme for the whole -- the entirety of the United States' claim, we have to talk about all of the things

that were alleged and what schemes were alleged.

The schemes that were alleged are more specifically talking about what was Medical Designs doing, what was Dr. Asfora doing, what was Sicage doing, how are the arrangements starting? Talking about the bullet cage. Although the bullet cage was FDA cleared long ago, it was substantially equivalent to other things.

And so like Your Honor has suggested earlier with questions, at that time Medical Designs was not finding very many users for the bullet cage. And so Dr. Asfora, as an owner and also as an agent, approached a number and a varied amount of other people, including his coworkers at Sanford, and also including just a random surgeon, a random neurosurgeon in the Dakota Dunes and expressly said I will give you "X" amount of money simply for you using this device.

And so that was alleged with particularity, and there was sufficient details of that whole theory of the case just talking about the bullet cage, in talking about Medical Designs, in talking about how money flowed between -- if Dr. Asfora is going to order a product that Medical Designs manufactures, like the bullet cage, he says I have a surgery on this date and I need "X" amount of screws, I need "X" amount of cages, and submits for -- you know, basically submits to Medical Designs this is

what I need, and those -- you know, the Medical Designs then bills Medicare for all of those devices, and eventually throughout the process distributes those proceeds back to Dr. Asfora. That's exactly the sort of harm and concern and the corruption of medical judgment that the Anti-Kickback Statute is intending to reach.

And so it's not just that; it's all of the schemes. It's about the bullet cage. It's about the SAMBA screw. It's about Sicage and how Sicage was created essentially to be a replacement billing source for Dr. Asfora, because he could no longer distribute -- or Medical Designs could no longer distribute the SAMBA screw because it was sold to Orthofix.

And so it really is sort of -- if we're talking about all of the schemes that the government has alleged, it has to be the entirety of the complaint and not just the medical necessity claims, which we'll get to.

And I can talk about, you know, the -- a lot of the really concerning evidence in those schemes. Not just those was kickbacks that we already discussed, where Dr. Asfora offered physicians money to use Medical Designs' products. But other things: A lot of secretive and furtive behavior as far as what Dr. Asfora told Sanford, what Dr. Asfora told CMS, what Dr. Asfora told -- through various forms and things like that.

But also Orthofix is a very big and important scheme that's discussed with extensive paragraphs in the complaint. And part of the reason that Orthofix is so concerning, Your Honor, is because Dr. Asfora, in that instance, had innovated, and he had brought something to market that other users besides himself were using -- the SAMBA screw -- to the point where it was sold to another distributor who wanted to distribute that product. And there was a lot of back and forth during the negotiation that's discussed in the complaint in detail and with particularity, and discusses throughout that whole process that Dr. Asfora's continuing to negotiate on behalf of Medical Designs, back and forth, back and forth. He wanted to be able to make money when he, himself, Dr. Asfora the physician, used the SAMBA screw at Sanford, at the Sioux Falls Specialty Hospital, and other places. And Orthofix had to come back repeatedly and say you can't get royalties off of your own use of the device. You don't want to violate the anti-kickback laws.

And there was this tension of continually going back and forth, continually going back and forth. And eventually there was a transfer in who could distribute the SAMBA screw, and Orthofix became the licensee or the distributor of that device. And still Dr. Asfora is constantly asking, I want Medical Designs to get it back,

just for my practice. I want to get it back, just for my practice. And to the point where he's saying again and again, I'm motivated to market my SI practice. I'm motivated to do more surgeries. And that's going on back and forth. And he's getting all these warnings for Orthofix.

And so all of these -- all of these allegations are viewed together about what's in Dr. Asfora's mind, what's happening between the business decisions of Medical Designs and Sicage with Dr. Asfora as an owner or agent, versus Dr. Asfora as the surgeon.

And so we've got the bullet cage instances. We've got the Orthofix instances, where eventually even though Medical Designs was not the distributor of SAMBA screw, Medical Designs continued anyway to distribute the SAMBA screw when Dr. Asfora was utilizing the SAMBA screw in a procedure and didn't tell Orthofix about that.

And thus he con -- Medical Designs continued to attempt to make money; and thus Dr. Asfora, in the process, continued to make money on a device that he had already sold.

And additionally with the Sicage, that's another variation, I suppose, on the kickback and ownership theory as it's discussed. Because Sicage was another example where it's an SI screw substantially equivalent to the

SAMBA screw that was sold to Orthofix, and Sicage was essentially a Dr. Asfora and Medical Designs, essentially Medical Designs as a distributor, can no longer catch the proceeds from utilizing an SI screw it developed, Medical Designs and Dr. Asfora developed, a substantially equivalent product.

And so then Medical Designs, which became Sicage, which is another sort of thing, Sicage was created as a separate LLC but it has a nearly identical address, the same employees, Dr. Asfora as the sole owner. But it's a separate entity. We'll admit that.

But that entity was created essentially, we believe the evidence shows and we've alleged and we've pled with particularity that for the purpose of Dr. Asfora and Medical Designs wanting to be able to capture the proceeds from his use of an SI screw at Sanford.

And so that sort of furtive and behavior of creating a new entity, depending on what was happening with the Orthofix agreement about the SAMBA screw, but this new entity and creating it to allow Sicage to distribute this SI screw for Dr. Asfora's use at Sanford.

So there's a lot of these sort of -- all these things are swirling together and I don't think can be set aside, especially when *Thayer* tells us what are the

particular details of the scheme? And that scheme includes the kickback theories, and that scheme includes the medical necessity claim.

But the second part, not just of the particular details of the scheme in *Thayer*, is we're talking about the reliable indicia. And so reliable indicia, in at least one case that's already been discussed today here where a court has decided what has constituted reliable indicia is that *Polukoff* case out of the Tenth Circuit. In there the Tenth Circuit found that the relater, who is the relater not the government in that case, had stated a claim where among other things that surgeon had allegedly performed an unusually large number of procedures; that other physicians had object the to the surgeon's practice; and procedures violated industry and hospital guidelines, which was discussed to some degree earlier here today.

And the government would suggest that the reading of the complaint at the pleadings stage, the reliable indicia that you have to look at and you have to consider is exactly that PARS data that Your Honor has already raised where as alleged in the complaint Sanford is giving Dr. Asfora essentially his risk score for the years of 2008 to 2014. And as we noted in the complaint, that risk score increased each year. I think during that period it doubled, various times, as we allege in the

complaint.

Eventually, in that last reporting year in 2014, Dr. Asfora was in the top .5 percent of all physicians, and I think was the 12th neurosurgeon among all neurosurgeons in the United States. And that's for his specialty. Neurosurgery is a high-end surgery. It's risky. You're in brains. You're in backs.

And so that's particularly relevant, I think in this case, when we're talking about the statistics or items like that, that the *Polukoff* court may have considered.

The physician complaints are particularly important in this case. Your Honor has already addressed that the relaters themselves -- one is a neurosurgeon; one is an orthopedic surgeon -- but both had overlapping practices with Dr. Asfora. And we can assume, I think, at this stage and based on all of the allegations in the complaint, there was a sharing of patients. And I think it was noted in the complaint that Dr. Bechtold is a specialist in hip procedures, and the hip is very close to the SI joint for the SAMBA screw that Sicage. And of course Dr. Roman, the other relater, is a partner or was a partner, neurosurgeon doing a lot of the same spine work.

But to be honest about the complaints that are specifically alleged in our complaints, the United States,

the controlling complaint, there was a Sanford physician -- and we've talked about that in the complaint at paragraph 133 -- that specifically said and was concerned that Dr. Asfora owns the company that makes the bullet cage, he has an income from his use of the cage. After the cage was FDA cleared he was using the cage also exclusively. He's doing a large number of multiple-level spinal fusions. And specifically this physician used the word "outlier."

And so that was particularly relevant and very specific, very detailed, talking about the owners with interest that we've already discussed, talking about the potential harm to patients as far as solely using just one device in which he has an ownership interest and receives money, doing a large number of multiple-level spinal fusions, which as you'll see in a lot of the external and internal peer reviews alleged in the complaint are called extremely rare in various circumstances. And we'll also see in those peer reviews that many are noted to be very dangerous to the patient, depending on the patient's characteristics.

And I'll get into those in the peer reviews. There were some internal peer reviews that we noted in the complaint. And there was one case in that instance, it was a five-level fusion; internally the committee that

reviewed it, there was eight Sanford surgeons that reviewed that case, and that was a specific instance where five bullet cages were used. Obviously we know Dr. -- Medical Designs and Dr. Asfora had an interest in bullet cages. That committee found that that procedure was aggressive in the situation -- that's at complaint paragraph 272. It varied from the standard of care. It was a lengthy procedure, meaning it may have been more expansive than necessary than what the patient's need was.

THE COURT: That's a -- just a moment. Just a moment. "Varied from the standard of care," well, that's the sort of thing that you hear in medical malpractice cases. But how much does that help you where we've got a fraud case?

MS. ROCHE: No, I think that's right, Your Honor. And we don't disagree that the standard is not whether somebody was negligent. I think the reason that we're using a lot of these -- a lot of these peer reviews, especially, is because they're independent at this point, and it's not the government's expert telling everyone that this is a medically unnecessary procedure. These are independent parties. And if we're talking about something to the effect of the degree to -- which we touched upon earlier, the *Polukoff* case did say that whether or not a specific procedure or -- is reasonable and necessary, you

can consider the appropriateness of the procedure, the duration and the frequency. Also, one that itemizes that the procedure be one that meets but that does not exceed the patient's medical need.

And so I think especially when you're dealing with the spine and levels, it is sort of a unique situation in comparison to stents or things like that, just because there are so many levels. And it's just a sort a different animal.

But we think all of this information is certainly relevant and is something that should be considered when we're talking about reliable indicia, when we're talking about schemes, when we know that Dr. Asfora has that ownership interest. And so a lot of these peer reviewers are saying why is there no documentation about why these two extra levels were done? Well, why -- why is this physician so aggressive? Or this sort of case would go to review in my hospital for analysis of what was done here.

And it's really to understand exactly what the government's concern here is that Dr. Asfora was motivated by greed and was motivated by making money. And at this stage the degree matters, I think, in the spine. Especially in some of these cases where the reviewers found that there was harm as a result of a procedure being

too long or being too aggressive. Because I think in one instance, at least, there was paraparesis; and I think that's the case that we're talking about presently, the internal purity case, the five-level fusion, and patient harm. And I think there was also the discussion of increase in surgical time. That can have dramatic harm on patients. The but that's just one of the examples. And that's with eight physicians reviewing it and coming to a consensus.

The external peer reviews we find are even more stark and even more helpful. Because -- you know, the common lay person may not know how often an internal purity process may happen. But an external purity process, you know, for the most part at this point, it's either eventually the government's expert that's talking about medical necessity, but here it's independent physicians with no stake in the outcome in this matter, and they're not being paid -- well, they're being paid, but not for the specific purpose of a litigation.

And there's this sort of distinction between whether or not the government can rely on these other cases if there's not a medical beneficiary. But again, we think it goes back to the way in which that we had to plead with particularity the scheme itself. And the scheme itself definitely involves how many devices

Dr. Asfora was using in a procedure, you know, for those 20 patient examples that was listed in the chart here, the defendants put up. We still think that those are relevant, especially understanding the ownership interests.

It's important for the Court to know, and it's relevant under the scheme as indicia how much money are we talking about here. Because in the response brief defendants routinely say things like Dr. Asfora wouldn't do something for a couple hundred dollars or, you know, thousands of dollars, or whatever. But there's some very high dollar amounts in those instances, and there's a lot of overlap between the products that Dr. Asfora has an ownership interest. So in a lot of cases there's SAMBA screws, there's bullet cages, there's Aegis screws, there's a surgical plate onto other devices that Medical Designs distributes. And so all of that is relevant.

While it may not be something that was actually submitted to Medicare or to a federal payer, it's still relevant when discussing *Thayer* in this larger idea of what's the scheme and what's the reliable indicia under *Thayer*.

And so the other two cases here, there's some really, really good language about -- at least in one case in the external peer review, it's a four-level fusion from

2012. And that was -- and in that instance Life Spine product was used. And in the previous case there was bullet cages used. And in the next case Life Spine products were used. And that's in the complaint in paragraphs 275 and 281. In there the reviewer found that the additional two --

THE COURT: Ma'am, whoa. Whoa. Two different cases, and I don't know what you're looking at. What are you talking about?

MS. ROCHE: I'm sorry. So we're talking about the four representative cases that the defendants have been discussing this their chart At the end of their complaint. There's three external peer review patients, essentially, that are discussed in the complaint. So the first one that I'm talking about is discussed in the complaint at paragraphs 275 and 281.

And it's really just to say to the Court that the reviewer there found that Dr. Asfora was aggressive, and that going additionally above two levels and adding two levels in a spinal surgery went against conventional neurosurgical teaching and practice.

But essentially at this point, I've been talking for a long time about it, but I think the important thing to note here is just that most of the -- the four example cases that we have, one that was an internal peer review

and three that were external peer reviews, are relevant to the analysis under *Thayer*. The 20 surgeries that were discussed in the complaint, and also that the defendants put on their example here in the slides, are all relevant and should be considered as far as what was motivating Dr. Asfora to do a lot of these surgeries.

And so I think *Thayer* tells us that the government's detailed recitations of the schemes involved here, with extensive allegations and extensive details about the scheme, and the reliable indicia that we just talked about and that Polukoff discussed are sufficient on their own to satisfy Rule 9(b) in this instance.

But as is sort have been alluded to here in the alternative, the government does have a representative example case. It is the case whose patient's name we will not say. But --

THE COURT: What paragraph are you looking at now?

MS. ROCHE: Yes, sir. Absolutely. So first we would be looking at in the complaint, this patient would be discussed at paragraph 282. And paragraph 282 notes that this patient was a Medicare beneficiary and has the date of birth year as 1942.

And then there's a discussion about in 287 and 288 of the complaint about the ways that a reviewer found

that the procedure discussed was aggressive, more specifically in the language that was actually used that this was a four-level fusion. And the reviewer noted that these are rare surgeries performed in a patient without spinal cord compression. The reviewer also noted here in 287 that the patient's complaints of mostly neck and arm pain could have been addressed with fewer levels included in the surgery. In 288 the reviewer also alleged that Asfora did not document in any of the paperwork associated with surgery or post-op care why he had extended the fusion into the upper thoracic spine. And the reviewer noted that they can be dangerous and rarely are performed, particularly in the case of the patient here.

And again, this is where the reviewer said that this case would be subject to peer review --

THE COURT: Excuse me. Let me ask a question. With regard to 288, you know, it says it would be -- such fusions can be dangerous and normally aren't performed particularly in degenerative spine cases like patient blank. In conclusion, the reviewer warned that in an academic medical center with peer review and other spine surgeons, such a case would quality for a morbidity and morality discussion.

What does that mean, a morbidity and morality discussion? I think that's code for -- what?

MS. ROCHE: I can't say that I know. I would just assume that it would be sort of round-tabled on what was done wrong, what was done right, correct or incorrect. But that's just me speculating at this time on that.

But I think the important part of that paragraph is that what was done was dangerous and rarely are performed, especially in this instance, talking about potential patient harm and also talking about going above and beyond what was necessary and reasonable for this patient based on this patient's symptoms and history and whatever the case may be.

And then importantly, as well, in the next paragraph, which is 289, the government alleges that then, thereafter, Sanford submitted those claims to Medicare for payment. And it was the amounts that were paid for the claim.

And also relevant is paragraph 38 of the government's complaint where the government alleges that for all of the complaint discussed in the complaint, meaning the specific patients, Dr. Asfora was certified to CMS that what we've done was reasonably and medically necessary.

THE COURT: Let me go back to 277, make sure you covered that. 277 where it say reported that the patient presented with no signs or symptoms of neurologic

dysfunction and had a normal EMG with no evidence of myopathy. To me, to the lay person, that means there wasn't a reason to operate on them. Am I misreading that?

MS. ROCHE: Are you in 287? Or 277?

THE COURT: 277.

MS. ROCHE: Oh, just one moment. Yes, I would agree with your lay interpretation of that, especially at the pleadings stage, which we don't yet have an expert. We will get an expert. Defendants will get an expert. Discovery where everyone will go through all of these medical records line by line and talk about what indications were there for surgery, what the history was, did they try any alternatives. Were there -- did they try therapy, did they try shots, did they try this, did they try that.

But I agree with Your Honor's assessment in this instance. And I think at least in one instance these reviewers would say things like, "if any procedure was necessary at all," or something, some qualifying language to that. And I would say that -- I would imagine that reviewers in the peer review setting are more -- withhold or use appropriate language more so than experts for both defendants and for the government would use when analyzing a case like this.

But yes, I agree with the Judge's assessment in

277.

All right. So as we just discussed in the representative example of the patient who will not be named, but at least in the information the Court is aware, and there's also as was discussed, essentially the United States has met its burden under 9(b); under either the *Thayer* test that we just discussed or the records of the example that was pleaded with particularity regarding that it was excessive care of this patient's procedure, that it was submitted to Medicare. It's also important that it involved an implant in which Medical Designs distributed the device and Dr. Asfora got monetary payment as a result.

So the next --

THE COURT: Let me ask you, let me ask you --

THE DEFENDANT: Yes, Your Honor.

THE COURT: If you -- hypothetically, if you haven't shown enough under 9(b) for pleading medical necessity, just hypothetically assume that, then why, in your lawsuit?

MS. ROCHE: Well, in theory what the kickback violation -- because we've claimed two varieties of falsity under the False Claims Act. And so the first version of the falsity, the ownership -- you know, the ownership theory or basically the violation of the

Anti-Kickback Statute remains. So that would be the stage unless there's an amended complaint in the future.

THE COURT: All right. Go ahead.

MS. ROCHE: All right. The next argument that defendants raise is sort of a blurring, talking about an objective standard or the need for sort of more of a bright line standard on what sort of -- and a type, I guess, of procedure. It's really talking about the degree sort of incident, again.

But I think this really goes to a broader sort of interpretation of objective falsity or whether or not medical necessity claims can be false, because medical judgments cannot be false. Which that theory should be rejected. That is not the clear law. The clear law is medical opinion can be false and are not shielded from scrutiny under the False Claims Act. And that's the *Polukoff* case.

And we're going back and forth talking about medical necessity claims and who's arguing which cases they didn't control. And this party is arguing that other cases control. But at the end of the day, all the parties can see that there are instances of medical necessity claims -- that in fact have survived the pleading stage of litigation, and have proceeded to discovery, have proceeded to trial, and have gotten past this point.

As far as I know, nothing in the case law suggests that there has to be this objective standard or that it has to be so clear-cut. I think the more helpful analysis when talking about what should be considered as far as medical judgment is really that medical opinions may trigger liability for fraud when they're not honestly held by their maker. And that's from the *Paulus* case, P-A-U-L-U-S, cited in our brief. Or when the speaker knows of facts that are fundamentally incompatible with his opinion. And that's, again, a Sixth Circuit case talking about medical judgment and opinions and when and how those should be sort of parsed.

And I guess it's really -- what we're saying sort of at this stage is really -- this isn't an appropriate determination to be making at the pleading stage, talking about who did what and who views what as being correct or incorrect or was standard for spinal surgery is the standard. And that's just really not what the law says or what we're required to do at the pleading stage. It clearly does much more.

If we get into discovery and are able to depose Dr. Asfora about specific surgeries and what was in his mind, what was not in his mind, and I think the *Paulus* case where it says opinions may trigger liability for fraud when they are not honestly held by their maker.

Considering the fact that Dr. Asfora has this financial incentive in the back of his mind for every procedure that he's doing, it can lead to the conclusion or the inference at this stage, based on the facts alleged in all the schemes, that his belief may not have been honestly held that all of the levels were necessary for the patients discussed in the complaint. But that's an issue for discovery. That's an issue for once the experts are involved and the medical records are discussed.

THE COURT: Just --

MS. ROCHE: I would also like to note --

THE COURT: I have a question. I have a question.

What about if Dr. Asfora with the same setup that he has with actually two corporations, what about if he would have not profited, but simply had office overhead for the two women that he had working in the office and the rent for the -- well, there were two offices, one right next to each other, I guess. And let's say that he didn't make a dime out of it and he was just -- you know, for whatever reason wanted to see his patented products all involved and in his patients.

If that were the case, would we have a violation under any theory?

MS. ROCHE: I don't know if I want to make a

bright line assertion on that step. But I do think that was -- that's the alternative for innovation. And that was the advice that he was given at the time of the Aegis agreement, essentially. You can do it if you want to, but make no profit, or don't make any money off of this because then you're not incentivized by your own surgical procedures.

So I think, you know, not locking in the government with that specific fact of Aegis, with the markup and -- again, depending on the facts. Because in the instance of Aegis, there were two other distributors in the Sioux Falls area that easily could have sold that product outside of Medical Designs. And Dr. Asfora and Medical Designs aren't involved in that transaction at all, and so there's no concern whatsoever rather than being smack dab in the middle of it.

But I would say for the most part that's definitely better; that's definitely closer to the true purpose of innovation and trying to make the medical field better. But it's not to say that physicians can't profit; it just has to be done more in line with the situation like the Orthofix agreement where there's royalties, and the physician continues to use that product in his or her practice as they normally would, understanding that they're not profiting off of it. Any royalties that that

surgeon makes from that legitimate innovation that's used by other people across the United States and maybe the world is that they make money off of the broad usage across the United States, and they don't make any money on their own use of the product. This is exactly what's at issue here.

And so I think it's hard to sort of step through a lot of those issues. But Aegis is a little bit difficult because, like I said, there was two other representatives that are discussed in the complaint, Pete Sanchez and Jesse Talcott, that were capable of distributing Aegis products without Medical Designs being in the middle.

And the bullet cages is different. The bullet cage is different because there's not really any other users of that product whatsoever, across the United States; which I think that's more appropriate for a trial argument or for discovery. But we do allege that it was essentially just Dr. Asfora after a certain time period that was utilizing the bullet cage.

And so the "take no profit" is much better, Your Honor, but just with those items that I noted as far as there was already distributors for Aegis, and that Dr. Asfora knows how to innovate and knows how to sell an invention to another company for the company to

distribute. And then he can still utilize the product and does not make a profit off of it.

THE COURT: Let me ask you another hypothetical. Let's assume, once again, that Dr. Asfora isn't making anything himself, it's just meeting the overhead on the selling of these devices, whichever device we're talking about. But let's assume further, though, that Dr. Asfora likes to operate, and he wouldn't normally make any money off of inserting any of his devices; nonetheless, he engaged in medically unnecessary surgery, for which he would have been paid his surgical fee but nothing more than that. Then would that then be a violation of -- under either of your theories?

MS. ROCHE: Yes. That would be a violation of the medical necessity theory. We wouldn't necessarily be able to establish that the claim was tainted by kickbacks, which is the first falsity argument. But the medical necessity concerns about being overly aggressive, billing Medicare as a result, providing more procedures or more extensive procedures than the patients need demanded, and we had similar sort of the indicia that we've talked about here. Maybe there's complaints, maybe there's -- maybe there is a standard that he's violating in spinal surgery as a result. But yes, I think that a plausible medical necessity claim, more likely than not, not a kickback

degree claim.

THE COURT: All right. You can go ahead.

MS. ROCHE: Furthermore, Your Honor, we're also talking about sort of a medical judgment question. And really I think that the *Palin* case, P-A-L-I-N, we cited in our brief is also relevant to the facts here, knowing that Dr. Asfora is profiting personally off of surgeries. In *Palin*, there a reasonable jury could find that defendant ordered the tests that were relevant in that case to generate income for themselves. I think based on all of the evidence that we've alleged in the complaints as far as generating income, interests in devices, and the amount of devices that Dr. Asfora implanted in patients, that the same result could be true; that a jury here could also find that the reason in part, in whole or in part, that Dr. Asfora performs at least the example case and any other cases that are found to be medically unnecessary in the discovery process, the jury could find that he performed maybe an entire surgery or more extensive surgeries than necessary; based on the fact that he was -- in whole or in part that he was making money off of those surgeries. So we think that *Palin* is also relevant there.

All right. The next allegation is talking about Dr. Asfora's knowledge about what he knew regarding whether or not certain of these claims alleged in the

complaint were medically unnecessary. Again, what Dr. Asfora knew will be determined more extensively after the pleading stage in discovery. But at this point -- at this point in the -- the *Reliance* case, which I think is helpful for the fact pattern here of where we are, the *Reliance* case is the Central District of California pleading, a case from 2014, cited in our brief. In there the Court found that if the United States is successful in proving that the physician investors received unlawful kickbacks for their use of certain devices, it is plausible to infer that defendants, those that offered the kickbacks or were the distributor of the device, knew that the physicians would do whatever it took to continue receiving such large kickbacks, including performing unnecessary or more extensive than necessary surgeries.

And so I think that *Reliance* could apply not just to Dr. Asfora, but could apply to Medical Designs and could apply to Sicage for the assumption that if kickbacks were involved, and I think if we've sufficiently pleaded at this stage, but further on if we prove that Dr. Asfora was receiving kickbacks from Medical Designs and some from Sicage, then it also leads to the inference that those folks would know that the doctor would do whatever it took to continue making money.

And also Dr. Asfora, you know, he -- it's all of

the things that we discussed earlier about all of the different learnings and all of the different things that folks have said that he, himself, was privy to as far as multi-level surgeries being too aggressive, his spinal surgeries being too extensive. I don't know any of those things standing alone is enough; but all of those things together, all of nine various warnings, the peer review processes, Dr. Asfora received all of the final findings of the internal peer review processes. That's alleged in the complaint. He saw the external peer reviews and has had access to the external peer reviews prior to this lawsuit.

So considering that the knowledge of what his partners thought and the relaters thought and the folks -- the physicians that complained about Dr. Asfora's practice and how it had changed, coupled with their viewing of the internal peer review, the external peer review, I think that leads to a plausible conclusion that Dr. Asfora knew that he was performing unnecessary medical procedures. And certainly, again, if you consider the kickback, that allegation being thrown in the mix, and looking at the *Reliance* case and understanding the plausible inferences from a kickback and leading to medically unnecessary procedures, I think we've satisfied that final element or that final argument that defendant's discussed on

Dr. Asfora's knowledge on medically unnecessary claims.

I just want to be sure, do any of my colleagues, did I leave anything out on the medical necessity piece or does the Court have further questions on the medical necessity piece?

THE COURT: No. I don't have any further questions. Thank you.

Does the defense have any rebuttal it wishes to make?

I've read a fair number of -- not all, but a fair number of the cases that were cited, but I'm not on a first-name name basis. And as you were going through, sometimes you would say this case or that case, you know, without citation, and only one name. Well, I'm not that familiar with the cases generally. So I would ask that you -- even though they're cited in your brief, with regard to the cases that you specifically referred to in your argument, send me a letter with a copy to the defendant that such was the case name in full and the citation to the case.

MS. ROCHE: Yes, Your Honor.

THE COURT: All right. Let me hear from the defense.

MR. GEYERMAN: Thank you, Your Honor. There's a lot there. But let me try to step back and map it out for

you as to how we see the claims are asserted and the doctrine fitting into the six dismissal arguments that we've asserted.

Early on in the presentation the government referred to there's many schemes, they're all swirling all around, it was this sort of big mass of different theories of a lot of different thing that were done wrong. But I think ultimately, and frankly in response to Your Honor's very good question, it became evident that they have two separate and distinct theories of liability. Because when you said if I dismiss the medical necessity theory, what's left? And they said, I have my ownership kickback theory.

They are asserting that there is an ownership kickback violation, and therefore a False Claims Act violation, whether or not there was any medically unnecessary surgeries performed. Analytically these are two separate and distinct theories.

So, on the ownership kickback theory -- and not to step on my colleague Mr. Graham's toes, but I think -- there's a couple of real big picture points that frankly the government can't contest, and we would submit are really the underlying point of our dismissal argument.

Number one: The government has never said that it is a violation of the Anti-Kickback Statute to own a medical device company, use that company's devices in your

surgeries, and three, take a profit distribution because you are an owner. That -- those are the three basic elements of their ownership kickback theory here. And yet, there is not a single case guidance from the Department of Health and Human Services or the Department of Justice that has ever said when those three conditions are satisfied, you have an Anti-Kickback Statute violation. Point one.

Point two: Dr. Asfora lived through the DuBay investigation. And coming out of that investigation it was known he owned Medical Designs, that he used products that Medical Designs manufactured in his surgeries, and that he took a profit distribution because he owned the company.

Those are the three basic facts that the government says are sufficient for them to make out a violation under their ownership kickback theory; and yet, they're the very facts that have never been found to be sufficient to state a claim, and they're the very facts that nobody ever told Dr. Asfora after the DuBay investigation created a problem.

So where there's all of these allegations in the complaint about this person told Dr. Asfora this might be risky, or this person told Dr. Asfora don't do that, at the end of the day, all they're suing him on under the

ownership kickback theory is owning a device company, using that device company's products, and taking a profit for distribution. Nothing else. Nothing else matters. And there's no well-put allegation in the complaint that would show that Dr. Asfora thought coming out of the DuBay investigation that it was inappropriate in any way for him to keep using product from his own company.

So those are big picture points on the ownership kickback theory; and nothing that the government said to you in that long presentation undermines any of those points, I would submit.

Now let's pick for the moment to the medical necessity theory.

THE COURT: You're putting -- wait a minute.

Let's talk about the DuBay case and the spin that you put on it, which in all -- I'm looking at the judgment on the pleadings. And I'm looking at a summary judgment motion. And I think it would be fair to say from my point of view that you're putting absolutely the best spin on the DuBay settlement possible. And I don't think that I look -- I should look at it in that manner.

Because it seems to me it actually required quite a bit of chutzpa to say that he comes out of that and he thinks that what he's doing is okay. I think the contrary is probably true.

But in any event, I can't see that on a motion for directed verdict -- or excuse me -- a judgment for judgment on the pleadings, that I should adopt your reading of DuBay.

MR. GEYERMAN: I would respond this way, Your Honor. Number one, the statute that's allegedly violated, the Anti-Kickback Statute, which requires a knowing and willful violation of the law -- so it's an even higher mens rea standard than it is a violation of the False Claims Act itself, which is a mere knowing violation of the law.

So number one, it's about the highest mens rea standard that you can get --

THE COURT: Just a second. Wait a minute. Wait a minute.

It seems to me that we're talking about a jury question. The claim is in the -- among other things in the complaint -- that he said now let's be quiet about this, let's do this undercover, and so on. That's what they're claiming. And that sounds to me like a jury question as to what is this fellow 's -- Dr. Asfora's state of mind when he tells this to people? He can say well, I didn't want the hospital people to think I'm making a lot of money, or whatever. We can have his explanation.

But we're talking about a fact question here with regard to somebody's state of mind, with regard to his scienter, and that isn't something that can be appropriate or that can be determined in a motion for judgment on the pleadings.

MR. GEYERMAN: Your Honor, we're simply asking you as the reader of this complaint, you believe they've asserted a plausible basis for all prima facie elements of the point. And where one of those prima facie elements is a knowing and willful violation of the Anti-Kickback Statute. And where it is an undisputed allegation that he lived through the DuBay investigation, and it's also undisputed that DuBay did not say it is impermissible to be an owner of Medical Designs and keep using your bullet cage, which is a product the patent of which is owned by Medical Designs, there's no allegation we submit anywhere that a reasonable person would infer from it, jeez, Dr. Asfora thought it would not -- he couldn't use the bullet cage and take profit distribution from Medical Designs. We just don't think that's in there.

Now, if you want to parse out some allegations about different products, you know, they did at one point in their complaint say there's six different schemes here, and they defined the schemes by different products -- you know, bullet cage is one, Life Spine product is another --

each of those different products might have a little bit different story that comes with it.

But the biggest one and the lead one they start with is the bullet cage, which was the entire focus of the DuBay investigation. And Medical Designs manufactures it, he uses it in his surgeries, and because of that in part Medical Designs takes a profit. Nobody told him that was inappropriate, and there is no allegation in the complaint that he ever thought that it was.

THE COURT: Wait a minute. Nobody tells him it's inappropriate? His own lawyer did, apparently.

MR. GEYERMAN: That allegation applies to only one of the two license agreements that happened years later. It doesn't have any application to deal with, I believe, five out of the six products in the complaint.

So the government wants to have its cake and eat it too here. In many respects they are saying there's multiple schemes because there's multiple products, and they're cherry-picking facts from one business deal and trying to imply that that suggests a belief in someone's mind that there is a kickback problem as to all six products.

If Your Honor thinks that that is a relevant fact for purposes of evaluating the plausibility of the claim, then we would submit the allegation goes no further

than its need; which as to the one license arrangement that that legal advice came in the context of. It has nothing to do with the other five products or five (indiscernible). That's my only point.

I think it has become apparent that analytically ownership kickback theory is to stand independent of a medical necessity theory, as Your Honor's really pointing question, and good questions, fleshed out for the government.

So now we'll talk for a moment about the medical necessity theory. First is the government spent a lot of time the proposition that under Eighth Circuit precedent they have to prove a representative example. The government reads *Thayer* as standing for the proposition that they don't have to. We actually believe that *Joshi* and both *Thayer* cases stand for the proposition that they do. If Your Honor thinks that that is a material dispute of law point, we would be happy to submit some additional briefing on that issue, if Your Honor would like. If the respective sample rule applies, we win.

They haven't alleged more than one patient here. And the rule is some repetitive examples, plural, not one example. And that one patient that they have where they critique the quality of the surgery, and is the federal issue, that's all thief got.

Your Honor asked a good question about how come in the prior complaints in this case there was a lot more information and search about unnecessary surgeries that for some unknown reason don't make it into this complaint. I'll draw my inferences, as others will about that, but we're left with one surgery for a federal beneficiary where they are making some critique on the quality of care.

Even if, however, Your Honor disagrees with us that they don't have to prove representative samples of a surgery that was medically unnecessary, we still have two different grounds on which you can dismiss the entire medical necessity claim.

Number one is that the nature of the allegations don't rise to the level of asserting a plausible medically unnecessary procedure. And we have on our slides, at least, put forward the full pleading on slide six of what we would say are, frankly, the four best cases --

THE COURT: Just a minute. Just a minute. Let me ask you specifically with regard to paragraph 277 in the complaint, where board certified neurological surgeon says that the patient presented no signs or symptoms of neurologic dysfunction, had a normal EMG with no evidence of myopathy, that indicates to me there wasn't any reason to operate on him.

MR. GEYERMAN: Well, Your Honor, that's not what the -- that's not the language that they used. And I'm not a doctor, so -- but the government didn't really know how to answer that question. And I submit we shouldn't be guessing about what that means from a medical perspective.

If you look at paragraph --

THE COURT: That wasn't the paragraph where I was at. I asked about -- but then I asked about another one was -- just a minute.

MR. GEYERMAN: I know. Actually, before you move off of 277 --

THE COURT: 277, I don't believe, is what I asked a question about. I asked a question about 288 was -- the review in an academic medical center peer review from other spinal surgeons, such a case would qualify for a morbidity and morality discussion.

That sound ominous to me, but I don't know in medical code what exactly that means. It sounds like morality? Morbidity? That's death.

MR. GEYERMAN: They certainly cast it with the intent that the reader is going to imply that it's something ominous. But that's my point, is to if they had attached the entire report that was provided by this reviewer, it would give the Court on a Rule (9)(d) analysis a chance to look at a much more bigger picture

and see it in context, what is this actually saying?

Now, I wanted to address 277 and 278 in particular, because that was another one of the paragraphs that you asked counsel what does this language mean? And then your reading of the last sentence of 277 was like there's nothing wrong with this patient, so why would you operate at all on them? If you look at the very next paragraph, 278, the thrust of the further commentary on that surgery seems to be -- it was appropriate to operate on vertebra C5-C6 and the C6 and 7 levels, but adding two more levels on top of that is what the reviewer took issue with.

So 278 may seem in conflict with 277, which may say this person had nothing wrong at all and therefore no surgery at all should have been performed on them. The allegations are in conflict with one another insofar as 278 suggests there was some amount of the surgery that was okay and it ended up what was done was just too much.

And as to 288, I would point you to the paragraph 287 immediately above that, which is about the same patient. And it's -- and there the comment is that the surgery that was performed is a rare surgery. It's not saying it's unprecedented. It's not saying no reasonable surgeon would have performed it.

And the last sentence of 287 is saying that the

doctor -- or that this reviewer thought that the symptoms could have been addressed with fewer levels.

Now, are we quibbling about what this means? We are. However, the standard for asserting plausity of lack of medical necessity is very high. It's not enough to say different surgeons would come to differing conclusions. That's just sort of your traditional debate about experts.

Medical -- lack of medical necessity means there was no medical justification, period; no reasonable surgeon could make the medical decision that this surgeon did. And we have cited four cases at the motion to dismiss stage (indiscernible) the nature of the allegations did not rise to the level of saying there was no medical justification at all.

And we would be happy in a nice pithy letter to send those citations to you, because they're obviously intermixed with our much longer brief, after this argument.

But I think we need to keep in mind just how difficult it is to assert plausibly a claim for lack of medical necessity. If you are using a surgery for a purpose that the medical community universally says it should not be used for, it could have said (indiscernible) this: If you are using a surgery that is shown to have no medical value at all, cases have said that's enough to

reach a motion to dismiss. But we have yet to see a case where allegations that are about this incremental of a disagreement, how many different levels of a spine fusion is too many, that is the proper basis.

The last two things I'll make, and then I will stand down.

There's two cases that the government's talked about. One was the *Palin* case, and they cited it in her argument for the proposition that it shows that -- how much this is a jury question. Respectfully, we think that the more appropriate cases to look at are motions to dismiss cases. Because those are the cases that are applying the standard that Your Honor has to apply right now, which is what allegations in a complaint meet a plausibility standard.

Once this case gets past the motion to dismiss stage and past the summary judgment stage, then when the jury returns a verdict, to overturn that verdict is going to be a no-reasonable-juror-could-find standard. And that's what *Palin* was applying, which is not the same standard that a court on a Rule 12 and 9(b) motion is considering. So I don't think *Palin* is the right standard to look at, because it's really in a different procedure posture, and therefore it's confusing.

Finally, as to the *Reliance* case out of the

Central District of California, the *Reliance* defendants did not include the defendant surgeon. And in that case the defendants were investors in a medical device company who are asserting that there were no plausible allegations of scienter. They were not making the additional argument that Dr. Asfora is making in this case, which is the allegations were insufficient to suggest that the surgery was unnecessary in the first place.

So we submit, quite frankly, this issue was given pretty short-shrift in the *Reliance* case. We felt very clearly as to making one argument as to the sufficiency of a lack of necessity allegations, which goes to falsity. And separate and apart from that, we're making allegations about the sufficiency of his supposed scienter, which is a separate and independent ground that a case could be dismissed on -- at the motion to dismiss phase.

And with that, I will stand down unless my colleague Mr. Graham has anything more to add. I appreciate your time.

MR. GRAHAM: Nothing at all. Thank you, Grant.

THE COURT: All right.

MS. ROCHE: Your Honor, can I just ask a quick question? I don't mind to interrupt you while you're thinking.

THE COURT: Beg pardon?

MS. ROCHE: I don't mean to interrupt you while you're thinking. Is it okay if I just ask one clarifying question?

THE COURT: Clarifying question of who?

MS. ROCHE: Of you. I was just going to say, we responded on medical necessity and got into the Anti-Kickback Statute violation somewhat in the middle of that. But if there's any other questions the Court has for us on DuBay or about anything else that was raised more close to the ownership theory that I haven't had a chance to respond to, I'm happy to answer those questions. But I also know we've been sitting here a long time and the Court has very thoroughly reviewed everything and asked great questions. But I just didn't want you to think that we've waived any of those arguments by --

THE COURT: I have no illusion that you've waved anything, I'll tell you that.

MS. ROCHE: But otherwise I'll be quiet unless you think of something you want me to answer for you.

THE COURT: No.

Well, the case is going -- I'm going to look a little more at the medical necessity pleading, because I think it's thin. Whether it's nothing -- I know, I spent plenty of time on this thing. But I wanted to hear

argument to see if it would help me.

And, you know, it's a 9(b) pleading. And I have to look to see if, you know, as the government in essence, it seems to me, urges that cumulatively is enough. And I want to, frankly, re-review things in light of argument on medical necessity.

On the kickback theory, the motion is denied. The cause of action stated that the only thing that I'm looking at -- and that's true, denied too, is the other alternate theories that were pled.

But on the medical necessity theory, I want to consider that further. I'll rule subsequently on the medical necessity theory.

Now, we have everybody together so I wanted to talk to you a bit about -- assuming just for purposes of discussion that this case survives summary judgment, then, you know, in scheduling I'm going to have to set time aside for the trial, assuming it gets to trial. So I realize it's very, very preliminary to be asking anybody anything, because we don't even have an answer yet. And I haven't ruled yet on the medical necessity theory.

But if that claim ultimately goes ahead, that would involve some evidence that won't be otherwise in the case, I think. But recognizing those limitations, while talking about it just generally, I wanted to know how long

the parties thought trying this case would last.

Some of you are familiar with me in trial; some of you aren't. I start at 9:00 in the morning and go to noon, starting usually at 1:00 and going until 5:00. And I don't set any time restraints upon anybody. The lawyers, if they're going to bore the jury, that's their risk.

And I have counsel approach the bench if there's something that -- for instance you think something should be coming into evidence and it isn't. I keep on sustaining an objection. I'll allow counsel to approach the bench, and I'll tell you what your problem is. You might be able to solve the problem, or it might be a dead duck on the issue. But at least we have them without having to send the jury out, and so on. But that doesn't mean I want people traipsing up to the bench all the time. But in order to facilitate evidence coming in, I'll do that.

And with regard to the jury, unless the COVID-19 pandemic is gone or substantially gone by the time we try this, instead of using a 12-person jury, which I would prefer, I would use an eight-person jury. I don't prefer those, because I think it's easier to get an unusual result. I think the 12-person has a leveling effect.

But we can't try -- well, we could try -- we can

try with as few as six, civilly. But I want to have alternates in case that we need them. So the eight will decide if they're there at the end of the case, of course. But if we lose one or two during the case, six can still decide the case.

So I know this is very preliminary, but I have to look at, at some point, in setting some time aside for this. So how long does the government think this case would last?

MS. ROCHE: It's hard to know, Judge, when we don't know if medical necessity -- like you said, we don't know if medical necessity would be included with all the experts that would be involved and medical records that would be shared back and forth. But I would say at least weeks, based on all the evidence? A couple weeks?

THE COURT: Are you talking about your side of it, or the whole works?

MS. ROCHE: Um, again, it's dependent on if there's experts --

THE COURT: Right.

MS. ROCHE: -- for the necessity of a piece. Probably the whole thing, I would imagine, could be done in a month? But I would defer to others and my DOJ colleagues, if they have opinions.

THE COURT: Um-hum. And then this is all super

preliminary, but I'm just trying to get a feeling for what the -- what others think. What does the defense think?

MR. GEYERMAN: Your Honor, we haven't consulted on that issue, so I don't think we're even really in a position to say something meaningful. But these cases generally are certainly multiple weeks.

THE COURT: That's a pretty safe estimate.

Yeah, I think it would vary a lot, depending on whether medical necessity goes ahead. And of course the rest of it is that even if I toss the medical necessity, the government's already alluded to the fact that they would try and strengthen their pleading. That would depend upon what they have to strengthen it with, of course.

Well, I think that's all that we can do today. Is there anything further from the government?

MS. ROCHE: Just to clarify, the only thing you're looking for us as we walk away is the letter with our authorities cited herein. Is that correct? Copying the other side?

THE COURT: Yes.

MS. ROCHE: Nothing further. Thank you.

THE COURT: All right. Anything further from the defense?

MR. GEYERMAN: No, Your Honor. Thank you for

your time today.

THE COURT: All right. Thank you. We're in recess.

(End of proceedings this date.)

COURT REPORTER'S CERTIFICATE

UNITED STATES DISTRICT COURT)
DISTRICT OF SOUTH DAKOTA) SS
WESTERN DIVISION)

I, Sheri L. Not Help Him, RPR, CRR, Official Court Reporter in and for the United States District Court, District of South Dakota,

DO HEREBY CERTIFY that I acted as such Court Reporter for the Motions Hearing of the within-entitled action, and that the foregoing transcript, pages 1 to 98, inclusive, is a true and complete transcript of my stenographic notes taken for said Motions Hearing on July 23, 2020.

All appearances of participants in this hearing were remotely by videoconference or telephonic conference.

Dated at Rapid City, South Dakota, this 16th day of October, 2020.

/s/ Sheri L. Not Help Him

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